AMENDMENTS TO THE DRAWINGS

Applicant submits herewith replacement drawing sheets for FIG. 3. No new matter has been added by way of this amendment.

Applicant's amended specification refers to "proximal end 10A" and "distal end 10B" of lead 10 in the description of FIG. 3. The attached replacement drawing sheet includes a new version of FIG. 3 incorporating reference numbers "10A" and "10B."

Attachment: Replacement Sheet (1)

REMARKS

This Amendment is responsive to the Office Action dated October 18, 2006. Applicant has amended the specification to further describe FIG. 3, which was included in the originally filed disclosure. Accordingly, no new matter has been added by way of the amendment to the specification. Applicant has also amended claims 1, 15, 22, 42, and 53. Claims 1-63 are pending.

Claim Rejection Under 35 U.S.C. § 102(b)

In the Office Action, the Examiner rejected claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63 under 35 U.S.C. § 102(b) as being anticipated by Dahl et al. (US 5,531,779, herein referred to as Dahl). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Dahl fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, with respect to Applicant's independent claim 1 as amended, Dahl fails to disclose or suggest a neurostimulation lead comprising a lead body having a proximal end and a distal end, a plurality of stimulation electrodes disposed adjacent the distal end of the lead body, and a fixation mechanism mounted to the lead body at a position between one of the plurality of stimulation electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, where the position is axially displaced from the plurality of stimulation electrodes. As FIG. 3 of Applicant's disclosure illustrates, the fixation mechanism and a plurality of stimulation electrodes are positioned at different locations on the lead body.

In support of the rejection of claim 1, the Office Action characterized ring electrodes 46 and 48 and wire filaments 50 of Dahl's disclosure as the plurality of electrodes and fixation mechanism of Applicant's claim 1. Dahl describes electrode structure 42 as including a pair of spaced ring electrodes 46 and 48 interconnected by a circumferential array of wire filaments 50. Ring electrode 48 is connected to a single conductor 52 to connect electrode assembly 42 to pulse

generator 10.[1] Applicant's claim 1 as amended requires that the fixation mechanism is axially displaced from a plurality of electrodes. In contrast, Dahl teaches a single electrode assembly that includes wire filaments 50, where each and every element of the electrode assembly is electrically connected to define a single electrode assembly sharing a polarity. As further evidence of the shared polarity of ring electrodes 46, 48 and wire filaments 50 of the Dahl electrode assembly is FIG. 6 and the description thereof, which shows and describes a single connector 52. As a result of the shared polarity and the interconnection of each of the elements of the electrode assembly taught by Dahl, the ring electrodes 46, 48 and wire filaments 50 taught by Dahl in no way amounts a fixation mechanism that is positioned at a location of the lead body that is axially displaced from a plurality of stimulation electrodes. Rather, the wire filaments 50 taught by Dahl are an integral part of a single stimulation electrode.

Each and every claim term must be given meaning, and the claimed invention as a whole must be considered. MPEP § 2141.02. Claim 1 clearly recites a plurality of stimulation electrodes in addition to a fixation mechanism that is axially displaced from the plurality of stimulation electrodes. Dahl does not teach an stimulation lead including both a plurality of stimulation electrodes and a fixation mechanism. FIG. 2 of Dahl illustrates two stent electrode structures 40 and 42. Even if one stent electrode structure is considered to be a stimulation electrode and the other stent electrode structure is considered to be a fixation mechanism, Dahl still does not teach a plurality of electrodes in addition to a fixation mechanism. For at least these reasons, Dahl fails to disclose or suggest each and every element of claim 1.

Similarly, Applicant's independent claims 22 and 42 recite a fixation mechanism that is positioned at a location of the lead body that is axially displaced from a plurality of electrodes, and independent claim 53 recites fixing means positioned at a location of the lead body that is axially displaced from a plurality of electrodes. For at least the reasons described with respect to claim 1, Dahl fails to disclose or suggest each and every requirement of claims 22, 42, and 53.

Dahl also fails to disclose or suggest wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal

[1] Dahl, column 5, lines 5-26.

joint, as required by claims 3, 24, and 55. Dahl makes no mention of joint strength and lacks any disclosure that would have suggested the requirements of claims 3, 24, and 55. Additionally, the Office Action failed to show how Dahl teaches the elements of claim 3, 24, and 55, and accordingly, does not meet its burden of showing anticipation of each and every element of claims 3, 24, and 55.

With respect to claim 45, Dahl fails to disclose or suggest detaching a distal end of each wire-like element and withdrawing the lead from the target site. Dahl does not disclose removing a lead from a target site and certainly does not disclose or suggest detaching a distal end of each wire-like element and withdrawing the lead from the target site. For at least these reasons, Dahl fails to disclose or suggest the requirements of claim 45.

Additionally, Dahl fails to disclose or suggest a restraint mechanism that restrains wire-like elements against expansion and includes a stylet, the stylet accommodated by an inner lumen of a neurostimulation lead, as recited by claims 10 and 31. Similarly, Dahl fails to disclose or suggest removing a restraint by withdrawing at least part of a stylet from a lumen of the lead, thereby releasing a fixation mechanism to expand, as recited by claim 43. The Office Action failed to show how Dahl teaches the elements of claim 10, 31, and 43, and accordingly, does not meet its burden of showing anticipation of each and every element of claims 10, 31, and 43. While Dahl describes using a stylet wire to position a distal end of an electrode at a location within a vessel,[2] Dahl does not disclose or suggest using a stylet as a restraint mechanism and thus, fails to meet teach each and every element of claims 10, 31, and 43.

With respect to claims 11 and 32, Dahl fails to disclose or suggest a lead body with an elastic portion that causes a diameter of the lead body portion to decrease when the lead body portion is stretched. Dahl describes an elastic stent electrode structure (i.e., a plurality of conductive wires[3]) that has a larger diameter and shorter length in its relaxed state than in its constrained state.[4] The diameter of the stent electrode structure may be reduced by increasing the

[2] Dahl, column 2, lines 49-54.
[3] *Id.* at column 2, lines 62-65.
[4] *Id.* at column 2, lines 42-56.

length of the stent electrode.[5] However, Dahl does not disclose or suggest a lead body with an elastic portion that causes a diameter of the lead body portion to decrease when the lead body portion is stretched. For at least these reasons, Dahl fails to meet the requirements of claims 11 and 32.

Similarly, claim 62 requires that the stylet provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion, and claim 63 requires the elastic portion of the lead body to decrease in length upon removal of the stylet. As described with respect to 10, 31, and 43, Dahl does not disclose or suggest using a stylet as a restraint mechanism and merely describes using a stylet to position a distal end of an electrode. Additionally, as described with respect to claims 11 and 32, Dahl does not disclose or suggest an lead body including an elastic portion. For at least these reasons, Dahl fails to disclose or suggest the requirements of claims 62 and 63.

Dahl fails to disclose or suggest a sacral lead, a pudendal nerve lead, or a spinal cord stimulation lead, as required by claims 21 and 59. Dahl describes electrodes that may be positioned in one of the great veins or arteries of the heart for treatment of cardiac arrhythmias. The electrodes are sized such that, "the diameter of the structure substantially corresponds with the diameter of the [interior vena cava]."[6] Dahl does not contemplate using the electrodes for other applications and does not disclose or suggest a lead that is configured for sacral, pudendal, or spinal cord applications. For at least these reasons, Dahl fails to disclose or suggest the requirements of claims 21 and 59.

Dahl fails to disclose each and every limitation set forth in claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claims 15 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Dahl; and rejected claims 4-6, 25-27, 56, and 57 over Dahl in view of Tu

[5] *Id.*
[6] *Id.* at column 3, lines 45-52.

et al. (US 6,077,298, herein referred to as Tu). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Initially, Applicant notes that Tu provides no teaching that would have overcome the deficiencies of Dahl with respect to the requirements Applicant's independent claims discussed above. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4-6, 15, 25-27, 36, 56, and 57 under 35 U.S.C. § 103(a), and the rejections of each of these claims should be withdrawn. Moreover, the applied references, either alone or in combination, fail to teach or suggest a number of the additional requirements recited in these claims.

Dahl fails to disclose or suggest a neurostimulation lead including at least four electrodes, as required by claims 15 and 36. In support of the rejection of claims 15 and 36, the Examiner stated that it would have been obvious to double the number of electrodes disclosed in Dahl because it is well known to duplicate parts. However, Applicant's amended independent claims 1 and 22, from which claims 15 and 36, respectively, depend, require a plurality of stimulation electrodes disposed adjacent a distal end of a lead body and a fixation mechanism that is positioned at a location of the lead body that is axially displaced from the plurality of electrodes.

As Applicant's disclosure recognizes, a plurality of stimulation electrodes enables electrical pulses to be delivered to a patient via selected subsets of electrodes, which may have selected polarities.[7] The apparatus taught by Dahl, on the other hand, does not teach a plurality of electrodes, much less an apparatus that permits particular electrode combinations to be selected.

Dahl discloses a stent electrode structure that contacts a vessel wall and allows substantially unimpeded blood flow through the electrode.[8] The Office Action characterized this electrode structure as a fixation element. As noted above, Dahl provides no teaching that discloses or suggests including electrodes on the lead body that are axially displaced from the fixation mechanism. According to the teachings of Dahl, the stent electrode structure holds the

[7] Applicant's disclosure at paragraphs 43 and 44.
[8] Dahl, column 3, lines 46-52.

catheter approximately in the center of the vein or artery, such that the stent electrode (i.e., wire filaments 50) contacts the inferior vena cava (IVC) wall to supply electrical shock therapy to the heart. Including additional electrodes, such as ring electrodes, on the catheter at a position axially displaced from the fixation mechanism would contradict the electrical stimulation technique taught by Dahl because the additional electrodes would not contact the vessel wall. Accordingly, it would not have been obvious to one skilled in the art to modify Dahl to include a plurality of stimulation electrodes axially displaced from the fixation mechanism.

In FIG. 2 and the description thereof, Dahl discloses two stent electrode structures, one positioned in the superior vena cava and the other at "the same level of the [right ventricle] apex," to provide a more comprehensive electric field as compared to a single electrode extending from above the plane of the top of the atrium to below the plane of the right ventricle apex.[9] Even if one stent electrode structure is considered to be a stimulation electrode and the other stent electrode structure is considered to be a fixation mechanism, Dahl still does not teach or suggest a plurality of electrodes in addition to a fixation mechanism.

In addition, it is unclear how the Dahl apparatus would deliver stimulation via a plurality of electrodes. The positions of each of the two stent electrode structures disclosed by Dahl suggest that stimulation energy provided by the two stent electrodes traverses the heart from the superior vena cava to the right ventricle apex. For example, the electrode positioned in the superior vena cava may act as an anode and the electrode positioned at the plane of the right ventricle apex may act as a cathode, allowing the electrical stimulation current to flow along the heart's natural current path. Dahl does not teach or suggest how this same electrical stimulation current path would be achieved via more than two electrodes. For at least these reasons Dahl fails to disclose or suggest a lead including a four or more electrodes in addition to a fixation mechanism, as recited by claims 15 and 36.

The applied references fail to disclose or suggest fixation means including one or more wire-like elements including a shape memory alloy, as required by Applicant's claims 4, 25, and 56; fixation means including one or more wire-like elements including a super-elastic material,

[9] *Id*, column 4, lines 57-60 and column 5, lines 26-34.

as required by claims 5, 26, and 57; and a fixation mechanism including one or more wire-like elements including Nitinol, as required by claims 6 and 27.

In support of the rejection of claims 4-6, 25-27, 56, and 57, the Office Action stated that it would have been obvious to modify the wire-like elements disclosed in Dahl to include the shape-memory Nitinol material disclosed in Tu, because the wire-like elements of Dahl provide an equivalent function as the stent disclosed by Tu. However, Tu describes using Nitinol to allow a stent to be collapsed into its unexpanded state to aid in retraction of the stent from a vessel of a patient.[10] Dahl does not contemplate removal of a catheter and certainly does not disclose or suggest retracting the electrode structures to aid in the removal of the catheter. It is unclear why one of ordinary skill in the art would have modified the Dahl catheter to include a retractable material as taught by Tu because Dahl does not disclose or suggest removal of the catheter. The applied references fail to disclose or suggest each and every requirement of claims 406, 25-27, 56, and 57.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4-6, 15, 25-27, 36, 56, and 57 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

[10] Tu, column 2, lines 45-54.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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